

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

**This Document Relates to All Actions**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

**TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA,  
INC., ACTAVIS PHARMA, INC., AND ACTAVIS LLC'S ANSWER AND  
AFFIRMATIVE DEFENSES TO PLAINTIFFS' THIRD AMENDED CONSOLIDATED  
ECONOMIC LOSS CLASS ACTION COMPLAINT**

Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Actavis Pharma, Inc., and Actavis LLC (together, "Teva"), by and through their counsel of record, hereby pleads its Answer and Affirmative Defenses to the Plaintiffs' Third Amended Consolidated Economic Loss Class Action Complaint ("Complaint") as to claims designated for trial in the March 18, 2024 "TPP Trial." Teva expressly reserves the right to amend or supplement this Answer and Affirmative Defenses, and/or to file, amend or supplement subsequent Answers and Affirmative Defenses to any and all other claims set out in the Complaint and/or set for subsequent trial.

Except as otherwise expressly set forth below, Teva denies knowledge or information sufficient to form a belief as to the truth or falsity of each and every allegation contained in the Complaint to the extent that such allegations refer or relate to persons or entities other than Teva. Any allegation, averment, contention or statement in the Complaint not specifically and unequivocally admitted is denied.

1. Teva admits Plaintiffs have filed the present action but denies that the action is properly brought or maintained as a class action. Teva admits that it manufactured and sold Valsartan containing drugs (VCDs). Teva denies the allegations of Paragraph 1 to the extent the allegations suggest liability or wrongdoing by Teva.

2. Teva denies the allegations contained in Paragraph 2 of the complaint.

3. Teva admits the VCDs at issue are the generic versions of the registered listed drugs (“RLDs”) Diovan®, Diovan HCT®, Exforge®, and Exforge HCT®. Teva admits that VCDs are drugs indicated for the treatment of hypertension. Teva denies the remaining allegations set forth in Paragraph 3 to the extent the allegations suggest liability or wrongdoing by Teva.

4. Teva denies the allegations contained in Paragraph 4 of the complaint.

5. Teva denies the allegations contained in Paragraph 5 of the complaint.

6. Teva denies the allegations contained in Paragraph 6 of the complaint.

7. Teva denies the allegations contained in Paragraph 7 of the complaint.

8. Teva denies the allegations contained in Paragraph 8 of the complaint.

9. Teva denies the allegations contained in Paragraph 9 of the complaint.

10. Teva denies the allegations contained in Paragraph 10 of the complaint.

11. Teva denies the allegations contained in Paragraph 11 of the complaint.

12. Teva denies the allegations contained in Paragraph 12 of the complaint.

13. Teva denies the allegations contained in Paragraph 13 of the complaint.

14. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 14 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 14 to the extent the allegations suggest liability or wrongdoing by Teva.

15. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 15 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 15 to the extent the allegations suggest liability or wrongdoing by Teva.

16. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 16 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 16 to the extent the allegations suggest liability or wrongdoing by Teva.

17. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 17 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 17 to the extent the allegations suggest liability or wrongdoing by Teva.

18. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 18 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 18 to the extent the allegations suggest liability or wrongdoing by Teva.

19. Teva denies making the alleged express or implied warranties, denies breaching any such warranties, denies that Plaintiff relied on any such warranties, and denies that it engaged in any “deception about the impurities.” Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the other allegations contained in Paragraph 19 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 19 to the extent the allegations suggest liability or wrongdoing by Teva.

20. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 20 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 20 to the extent the allegations suggest liability or wrongdoing by Teva.

21. Teva denies making the alleged express or implied warranties, denies breaching any such warranties, denies that Plaintiff relied on any such warranties, and denies that it engaged in any “deception about the impurities.” Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the other allegations contained in Paragraph 21 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 21 to the extent the allegations suggest liability or wrongdoing by Teva.

22. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 22 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 22 to the extent the allegations suggest liability or wrongdoing by Teva.

23. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 23 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 23 to the extent the allegations suggest liability or wrongdoing by Teva.

24. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 24 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 24 to the extent the allegations suggest liability or wrongdoing by Teva.

25. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 25 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 25 to the extent the allegations suggest liability or wrongdoing by Teva.

26. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 26 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 26 to the extent the allegations suggest liability or wrongdoing by Teva.

27. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 27 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 27 to the extent the allegations suggest liability or wrongdoing by Teva.

28. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 28 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 28 to the extent the allegations suggest liability or wrongdoing by Teva.

29. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 29 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 29 to the extent the allegations suggest liability or wrongdoing by Teva.

30. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 30 of the Complaint, and therefore denies same. Teva

denies the allegations of Paragraph 30 to the extent the allegations suggest liability or wrongdoing by Teva.

31. Teva denies making the alleged express or implied warranties, denies breaching any such warranties, denies that Plaintiff relied on any such warranties, and denies that it engaged in any “deception about the impurities.” Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the other allegations contained in Paragraph 31 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 31 to the extent the allegations suggest liability or wrongdoing by Teva.

32. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 32 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 32 to the extent the allegations suggest liability or wrongdoing by Teva.

33. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 33 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 33 to the extent the allegations suggest liability or wrongdoing by Teva.

34. Teva denies making the alleged express or implied warranties, denies breaching any such warranties, denies that Plaintiff relied on any such warranties, and denies that it engaged in any “deception about the impurities.” Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the other allegations contained in Paragraph 34 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 34 to the extent the allegations suggest liability or wrongdoing by Teva.

35. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 35 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 35 to the extent the allegations suggest liability or wrongdoing by Teva.

36. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 36 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 36 to the extent the allegations suggest liability or wrongdoing by Teva.

37. Teva denies making the alleged express or implied warranties, denies breaching any such warranties, denies that Plaintiff relied on any such warranties, and denies that it engaged in any “deception about the impurities.” Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the other allegations contained in Paragraph 37 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 37 to the extent the allegations suggest liability or wrongdoing by Teva.

38. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 38 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 38 to the extent the allegations suggest liability or wrongdoing by Teva.

39. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 39 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 39 to the extent the allegations suggest liability or wrongdoing by Teva.

40. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 40 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 40 to the extent the allegations suggest liability or wrongdoing by Teva.

41. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 41 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 41 to the extent the allegations suggest liability or wrongdoing by Teva.

42. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 42 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 42 to the extent the allegations suggest liability or wrongdoing by Teva.

43. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 43 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 43 to the extent the allegations suggest liability or wrongdoing by Teva.

44. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 44 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 44 to the extent the allegations suggest liability or wrongdoing by Teva.

45. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 45 of the Complaint, and therefore denies same. Teva



denies the allegations of Paragraph 45 to the extent the allegations suggest liability or wrongdoing by Teva.

46. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 46 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 46 to the extent the allegations suggest liability or wrongdoing by Teva.

47. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 47 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 47 to the extent the allegations suggest liability or wrongdoing by Teva.

48. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 48 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 48 to the extent the allegations suggest liability or wrongdoing by Teva.

49. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 49 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 49 to the extent the allegations suggest liability or wrongdoing by Teva.

50. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 50 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 50 to the extent the allegations suggest liability or wrongdoing by Teva.

51. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 51 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 51 to the extent the allegations suggest liability or wrongdoing by Teva.

52. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 52 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 52 to the extent the allegations suggest liability or wrongdoing by Teva.

53. Teva denies making the alleged express or implied warranties, denies breaching any such warranties, denies that Plaintiff relied on any such warranties, and denies that it engaged in any “deception about the impurities.” Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the other allegations contained in Paragraph 53 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 53 to the extent the allegations suggest liability or wrongdoing by Teva.

54. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 54 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 54 to the extent the allegations suggest liability or wrongdoing by Teva.

55. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 55 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 55 to the extent the allegations suggest liability or wrongdoing by Teva.

56. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 56 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 56 to the extent the allegations suggest liability or wrongdoing by Teva.

57. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 57 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 57 to the extent the allegations suggest liability or wrongdoing by Teva.

58. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 58 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 58 to the extent the allegations suggest liability or wrongdoing by Teva.

59. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 59 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 59 to the extent the allegations suggest liability or wrongdoing by Teva.

60. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 60 of the Complaint, and therefore denies same.

61. Teva denies that MSPRC has standing to bring this action. Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 61 of the Complaint, and therefore denies same.

62. Teva denies that MSPRC has standing to bring this action. Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 62 of the Complaint, and therefore denies same.

63. Teva denies it is a “liable entity.” Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 63 of the Complaint, and therefore denies same.

64. Teva denies it is a “liable entity.” Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 64 of the Complaint, and therefore denies same.

65. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 65 of the Complaint, and therefore denies same.

66. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 66 of the Complaint, and therefore denies same.

67. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 67 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 67 to the extent the allegations suggest liability or wrongdoing by Teva.

68. Teva admits that it manufactured and sold VCDs in the United States pursuant to FDA approval. Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 68 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 68 to the extent the allegations suggest liability or wrongdoing by Teva.

69. Teva denies that the allegations of paragraph 69 demonstrate standing. Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 69 of the Complaint, and therefore denies same.

70. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 70 of the Complaint, and therefore denies same.

71. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 71 of the Complaint, and therefore denies same.

72. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 72 of the Complaint, and therefore denies same.

73. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 73 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 73 to the extent the allegations suggest liability or wrongdoing by Teva.

74. Paragraph 74 of the Complaint does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent a response is required, Teva denies the allegations of Paragraph 74 to the extent the allegations suggest liability or wrongdoing by Teva.

75. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 75 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 75 to the extent the allegations suggest liability or wrongdoing by Teva.

76. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 76 of the Complaint, and therefore denies same. Teva

denies the allegations of Paragraph 76 to the extent the allegations suggest liability or wrongdoing by Teva.

77. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 77 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 77 to the extent the allegations suggest liability or wrongdoing by Teva.

78. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 78 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 78 to the extent the allegations suggest liability or wrongdoing by Teva.

79. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 79 of the Complaint, and therefore denies same.

80. Teva admits it purchased certain API from ZHP. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 80 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 80 to the extent the allegations suggest liability or wrongdoing by Teva.

81. Paragraph 81 appears to be directed at the ZHP entities, and as such Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 81 of the Complaint, and therefore denies same.

82. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 82 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 82 to the extent the allegations suggest liability or wrongdoing by Teva.

83. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 83 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 83 to the extent the allegations suggest liability or wrongdoing by Teva.

84. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 84 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 84 to the extent the allegations suggest liability or wrongdoing by Teva.

85. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 85 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 85 to the extent the allegations suggest liability or wrongdoing by Teva.

86. Paragraph 86 of the Complaint does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 86 of the Complaint, and therefore denies same.

87. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 87 of the Complaint, and therefore denies same.

88. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 88 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 88 to the extent the allegations suggest liability or wrongdoing by Teva.

89. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 89 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 89 to the extent the allegations suggest liability or wrongdoing by Teva.

90. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 90 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 90 to the extent the allegations suggest liability or wrongdoing by Teva.

91. Paragraph 91 of the Complaint does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 91 of the Complaint, and therefore denies same.

92. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 92 of the Complaint, and therefore denies same.

93. Teva admits it purchased certain API from Mylan. Teva denies the allegations of Paragraph 93 to the extent the allegations suggest liability or wrongdoing by Teva.

94. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 94 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 94 to the extent the allegations suggest liability or wrongdoing by Teva.

95. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 95 of the Complaint, and therefore denies same. Teva denies



the allegations of Paragraph 95 to the extent the allegations suggest liability or wrongdoing by Teva.

96. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 96 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 96 to the extent the allegations suggest liability or wrongdoing by Teva.

97. Paragraph 97 of the Complaint does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 97 of the Complaint, and therefore denies same.

98. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 98 of the Complaint, and therefore denies same.

99. Teva admits that Teva Pharmaceutical Industries Ltd. is a foreign company headquartered in Petah Tikvah, Israel. Teva denies the remainder of the allegations in Paragraph 99 of the Complaint.

100. Teva admits that it is an indirect wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. Teva denies the remainder of the allegations in Paragraph 100 of the Complaint.

101. Teva admits that it is an indirect wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. Teva denies the remainder of the allegations in Paragraph 101 of the Complaint.

102. Teva admits that it is an indirect wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. Teva denies the remainder of the allegations in Paragraph 102 of the Complaint.

103. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 103 of the Complaint, and therefore denies same. Teva

denies the allegations of Paragraph 103 to the extent the allegations suggest liability or wrongdoing by Teva.

104. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 104 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 104 to the extent the allegations suggest liability or wrongdoing by Teva.

105. Paragraph 105 of the Complaint does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 105 of the Complaint, and therefore denies same.

106. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 106 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 106 to the extent the allegations suggest liability or wrongdoing by Teva.

107. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 107 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 107 to the extent the allegations suggest liability or wrongdoing by Teva.

108. Paragraph 108 of the Complaint does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 108 of the Complaint, and therefore denies same.

109. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 109 of the Complaint, and therefore denies same.

110. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 110 of the Complaint, and therefore denies same.

111. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 111 of the Complaint, and therefore denies same.

112. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 112 of the Complaint, and therefore denies same.

113. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 113 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 113 to the extent the allegations suggest liability or wrongdoing by Teva.

114. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 114 of the Complaint, and therefore denies same.

115. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 115 of the Complaint, and therefore denies same.

116. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 116 of the Complaint, and therefore denies same.

117. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 117 of the Complaint, and therefore denies same.

118. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 118 of the Complaint, and therefore denies same.

119. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 119 of the Complaint, and therefore denies same.

120. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 120 of the Complaint, and therefore denies same.

121. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 121 of the Complaint, and therefore denies same.

122. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 122 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 122 to the extent the allegations suggest liability or wrongdoing by Teva.

123. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 123 of the Complaint, and therefore denies same.

124. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 124 of the Complaint, and therefore denies same.

125. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 125 of the Complaint, and therefore denies same.

126. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 126 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 126 to the extent the allegations suggest liability or wrongdoing by Teva.

127. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 127 of the Complaint, and therefore denies same.

128. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 128 of the Complaint, and therefore denies same.

129. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 129 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 129 to the extent the allegations suggest liability or wrongdoing by Teva.

130. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 130 of the Complaint, and therefore denies same.

131. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 131 of the Complaint, and therefore denies same.

132. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 132 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 132 to the extent the allegations suggest liability or wrongdoing by Teva.

133. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 133 of the Complaint, and therefore denies same.

134. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 134 of the Complaint, and therefore denies same.

135. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 135 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 135 to the extent the allegations suggest liability or wrongdoing by Teva.

136. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 136 of the Complaint, and therefore denies same.

137. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 137 of the Complaint, and therefore denies same.

138. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 138 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 138 to the extent the allegations suggest liability or wrongdoing by Teva.

139. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 139 of the Complaint, and therefore denies same.

140. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 140 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 140 to the extent the allegations suggest liability or wrongdoing by Teva.

141. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 141 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 141 to the extent the allegations suggest liability or wrongdoing by Teva.

142. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 142 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 142 and the corresponding footnote 14 to the extent the allegations suggest liability or wrongdoing by Teva.

143. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 143 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 143 to the extent the allegations suggest liability or wrongdoing by Teva.

144. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 144 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 144 to the extent the allegations suggest liability or wrongdoing by Teva.

145. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 145 of the Complaint, and therefore denies same.

146. Paragraph 146 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations contained in Paragraph 146 of the Complaint.

147. Paragraph 147 of the Complaint does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 147 of the Complaint, and therefore denies same.

148. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 148 of the Complaint, and therefore denies same.

149. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 149 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 149 to the extent the allegations suggest liability or wrongdoing by Teva.

150. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 150 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 150 to the extent the allegations suggest liability or wrongdoing by Teva.

151. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 151 of the Complaint, and therefore denies same.

152. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 152 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 152 to the extent the allegations suggest liability or wrongdoing by Teva.

153. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 153 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 153 to the extent the allegations suggest liability or wrongdoing by Teva.

154. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 154 of the Complaint, and therefore denies same.

155. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 155 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 155 to the extent the allegations suggest liability or wrongdoing by Teva.

156. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 156 of the Complaint, and therefore denies same. Teva



denies the allegations of Paragraph 156 to the extent the allegations suggest liability or wrongdoing by Teva.

157. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 157 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 157 to the extent the allegations suggest liability or wrongdoing by Teva.

158. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 158 of the Complaint, and therefore denies same.

159. Teva admits Major is a repackager for certain VCDs manufactured by Teva which contained API from Defendant Zhejiang Huahai Pharmaceutical Co., Ltd.

160. Teva denies the allegations of Paragraph 160 to the extent the allegations suggest liability or wrongdoing by Teva. Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 160, and therefore denies same.

161. Teva admits AvKARE, Inc. is a repackager for certain VCDs manufactured by Teva. Teva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 161 of the Complaint, and therefore denies same.

162. Teva denies the allegations of Paragraph 162 to the extent the allegations suggest liability or wrongdoing by Teva. Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 162, and therefore denies same.

163. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 163 of the Complaint, and therefore denies same. Teva

denies the allegations of Paragraph 163 to the extent the allegations suggest liability or wrongdoing by Teva.

164. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 164 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 164 to the extent the allegations suggest liability or wrongdoing by Teva.

165. Paragraph 165 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations contained in Paragraph 165 of the Complaint.

166. Paragraph 166 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations contained in Paragraph 166 of the Complaint.

167. Paragraph 167 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations contained in Paragraph 167 of the Complaint.

168. Teva admits that as a pharmaceutical manufacturer it is part of the pharmaceutical supply chain. Except as stated, Teva admits that manufacturers, wholesalers, pharmacies, and PBMs are part of the general pharmaceutical supply chain in the United States, and is without knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 168 of the Complaint, and therefore denies same.

169. Teva admits from time to time it produces drugs which are sold to wholesalers and may be further sold to retail or mail-order pharmacies for dispensation to patients with valid prescriptions. Teva is without knowledge or information sufficient to form a belief as to the truth

of the remaining allegations contained in Paragraph 169 of the Complaint, and therefore denies same.

170. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 170 of the Complaint, and therefore denies same.

171. Teva denies the allegations of Paragraph 171.

172. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 172 of the Complaint, and therefore denies same.

173. Paragraph 173 of the Complaint does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent that a response is required, denied.

174. Teva admits that approved pharmaceutical products are assigned NDCs. Teva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 174 of the Complaint, and therefore denies same.

175. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 175 of the Complaint, and therefore denies same.

176. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 176 of the Complaint, and therefore denies same.

177. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 177 of the Complaint, and therefore denies same.

178. Teva admits that Lot numbers may be used to report certain issues arising from a particular prescription drug. Teva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 178 of the Complaint, and

therefore denies same. Teva denies the allegations of Paragraph 178 to the extent the allegations suggest liability or wrongdoing by Teva.

179. Paragraph 179 of the Complaint recites legal conclusions, and so no answer is required. Paragraph 179 also contains a quotation from a publicly available document. That document speaks for itself. To the extent that an answer is required, Teva denies the allegations contained in Paragraph 179 of the Complaint.

180. Paragraph 180 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations contained in Paragraph 180 of the Complaint.

181. Teva admits that it maintained certain information about its manufactured products prior to the enactment of the DSCSA and that some of the information maintained prior to the enactment of the DSCSA is also maintained after the enactment of the DSCA. Teva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 181 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 181 to the extent the allegations suggest liability or wrongdoing by Teva.

182. Paragraph 182 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations contained in Paragraph 182 of the Complaint.

183. Paragraph 183 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations contained in Paragraph 183 of the Complaint.

184. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 184 of the Complaint, and therefore denies same.

185. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 185 of the Complaint, and therefore denies same.

186. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 186 of the Complaint, and therefore denies same.

187. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 187 of the Complaint, and therefore denies same.

188. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 188 of the Complaint, and therefore denies same.

189. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 189 of the Complaint, and therefore denies same.

190. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 190 of the Complaint, and therefore denies same.

191. Paragraph 191 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva is without knowledge or information sufficient to form a belief as to the accuracy of the characterization of the DSCSA contained in Paragraph 191 of the Complaint, and therefore denies same.

192. Paragraph 192 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva is without knowledge or information sufficient to form a belief as to the accuracy of the characterization of the DSCSA contained in Paragraph 192 of the Complaint, and therefore denies same.

193. Paragraph 193 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva admits that Paragraph 193 appears to

contain a partial quotation of the DSCSA, and denies any remaining allegations contained in Paragraph 193 of the Complaint.

194. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 194 of the Complaint, and therefore denies same.

195. Paragraph 195 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva admits its VCD products have NDC codes. Teva denies the allegations of Paragraph 195 to the extent the allegations suggest liability or wrongdoing by Teva.

196. Teva admits that recalled VCDs were identified in part by their NDCs. Teva denies the remaining allegations of Paragraph 196.

197. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 197 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 197 to the extent the allegations suggest liability or wrongdoing by Teva.

198. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 198 of the Complaint, and therefore denies same.

199. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 199 of the Complaint, and therefore denies same.

200. Teva states that the FDA announcement referenced in Paragraph 200 of the Complaint speaks for itself. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 200 of the Complaint, and therefore denies same.

201. Teva states that the McKesson announcement referenced in Paragraph 201 of the Complaint speaks for itself. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 201 of the Complaint, and therefore denies same.

202. Teva states that the Rite-Aid announcement referenced in Paragraph 202 of the Complaint speaks for itself. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 202 of the Complaint, and therefore denies same.

203. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 203 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 203 to the extent the allegations suggest liability or wrongdoing by Teva.

204. Teva states that the quotation referenced in Paragraph 204 of the Complaint speaks for itself. To the extent a response is required, Teva denies the allegations of Paragraph 204 to the extent the allegations suggest liability or wrongdoing by Teva.

205. Teva admits that pharmaceutical manufacturers are permitted to submit an ANDA for approval of generic medications and that such ANDA must meet the requirements set forth by federal statute and implementing regulations. Except as thus stated, the allegations in Paragraph 205 misquote or mischaracterize a writing, and Teva therefore denies the remaining allegations in Paragraph 205.

206. Teva admits every VCD it manufactured was approved by the FDA pursuant to one or more properly submitted ANDAs. Teva lacks information or knowledge sufficient to admit or deny the allegations to the extent the pertain to other medications. Teva denies the remaining

allegations of Paragraph 206 of the Complaint to the extent the allegations suggest liability or wrongdoing by Teva.

207. The allegations in Paragraph 207 misquote or mischaracterize a writing, and Teva therefore denies the allegations in Paragraph 207. Teva denies the allegations of Paragraph 207 to the extent the allegations suggest liability or wrongdoing by Teva.

208. The allegations in Paragraph 208 misquote or mischaracterize a writing, and Teva therefore denies the allegations in Paragraph 208. Teva denies the allegations of Paragraph 208 to the extent the allegations suggest liability or wrongdoing by Teva.

209. Paragraph 209 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations of Paragraph 209 to the extent the allegations suggest liability or wrongdoing by Teva.

210. Paragraph 210 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations of Paragraph 210 to the extent the allegations suggest liability or wrongdoing by Teva.

211. Paragraph 211 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations of Paragraph 211 to the extent the allegations suggest liability or wrongdoing by Teva.

212. Paragraph 212 of the Complaint recites legal conclusions, and so no answer is required. Paragraph 212 also contains quotations which speak for themselves. To the extent that an answer is required, Teva denies the allegations of Paragraph 212 to the extent the allegations suggest liability or wrongdoing by Teva.

213. Paragraph 213 of the Complaint recites legal conclusions, and so no answer is required. Paragraph 213 also contains quotations which speak for themselves. To the extent that



an answer is required, Teva denies the allegations of Paragraph 213 to the extent the allegations suggest liability or wrongdoing by Teva.

214. Teva denies the allegations contained in Paragraph 214 of the complaint.

215. Teva states that the quotation in Paragraph 215 of the Complaint speaks for itself. To the extent a response is required, Teva denies the allegations of Paragraph 215 to the extent the allegations suggest liability or wrongdoing by Teva.

216. Teva states that the quotation in Paragraph 216 of the Complaint speaks for itself. To the extent a response is required, Teva denies the allegations of Paragraph 216 to the extent the allegations suggest liability or wrongdoing by Teva.

217. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 217 of the Complaint, and therefore denies same.

218. Teva denies the allegations contained in Paragraph 218 of the complaint.

219. Teva denies the allegations contained in Paragraph 219 of the Complaint.

220. Teva denies the allegations contained in Paragraph 220 of the complaint.

221. Teva denies the allegations contained in Paragraph 221 of the complaint.

222. Teva denies the allegations contained in Paragraph 222 of the Complaint.

223. Teva denies the allegations contained in Paragraph 223 of the Complaint.

224. Teva denies the allegations contained in Paragraph 224 of the Complaint.

225. Teva states that the quotations in Paragraph 225 of the Complaint speaks for itself. To the extent a response is required, Teva denies the allegations of Paragraph 225 to the extent the allegations suggest liability or wrongdoing by Teva.

226. Teva states that the quotations in Paragraph 226 of the Complaint speaks for itself. To the extent a response is required, Teva denies the allegations of Paragraph 226 to the extent the allegations suggest liability or wrongdoing by Teva.

227. Teva states that the quotations in Paragraph 227 of the Complaint speaks for itself. To the extent a response is required, Teva denies the allegations of Paragraph 227 to the extent the allegations suggest liability or wrongdoing by Teva.

228. Paragraph 228 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations of Paragraph 228 to the extent the allegations suggest liability or wrongdoing by Teva.

229. Teva denies the allegations contained in Paragraph 229 of the Complaint.

230. Teva denies the allegations contained in Paragraph 230 of the Complaint.

231. Teva denies the allegations contained in Paragraph 231 of the Complaint.

232. Teva admits the generic drug supply chain for VCDs involves multiple parties. Except as stated, denied.

233. Teva admits the supply chain for VCDs may involve generic drug manufacturers, API suppliers, repackagers and/or labelers. Except as stated, Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 233 of the Complaint, and therefore denies same.

234. Teva admits that generic drug manufacturers may contract with wholesalers and retail pharmacies for the sale of generic pharmaceutical products. Except as thus stated, denied.

235. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 235 of the Complaint, and therefore denies same.

236. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 236 of the Complaint, and therefore denies same.

237. Teva denies the allegations contained in Paragraph 237 of the Complaint.

238. Teva states that the quotation in Paragraph 238 of the Complaint speaks for itself. To the extent a response is required, Teva denies the allegations of Paragraph 238 to the extent the allegations suggest liability or wrongdoing by Teva.

239. Teva states that the FDA regulations cited in Paragraph 239 speak for themselves. To the extent a response is required, Teva denies the allegations of Paragraph 239 to the extent the allegations suggest liability or wrongdoing by Teva.

240. Paragraph 240 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations of Paragraph 240 to the extent the allegations suggest liability or wrongdoing by Teva.

241. Teva states that the federal regulation quoted in Paragraph 241 speaks for itself. Paragraph 241 of the Complaint also recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations of Paragraph 241 to the extent the allegations suggest liability or wrongdoing by Teva.

242. Teva states that the federal regulation quoted in Paragraph 242 speaks for itself. To the extent that an answer is required, Teva denies the allegations of Paragraph 242 to the extent the allegations suggest liability or wrongdoing by Teva.

243. Teva states that the federal regulation quoted in Paragraph 243 speaks for itself. To the extent that an answer is required, Teva denies the allegations of Paragraph 243 to the extent the allegations suggest liability or wrongdoing by Teva.

244. Teva states that the federal regulation quoted in Paragraph 244 speaks for itself. To the extent that an answer is required, Teva denies the allegations of Paragraph 244 to the extent the allegations suggest liability or wrongdoing by Teva.

245. Teva states that the federal regulation quoted in Paragraph 245 speaks for itself. To the extent that an answer is required, Teva denies the allegations of Paragraph 245 to the extent the allegations suggest liability or wrongdoing by Teva.

246. Paragraph 246 of the Complaint recites legal conclusions, and so no answer is required. To the extent an answer is required, Teva admits the Drug Price Competition and Patent Term Restoration Act of 1984 is codified at 21 U.S.C. § 355(j) and is referred to as the Hatch-Waxman Amendments.

247. Paragraph 247 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations of Paragraph 247 to the extent the allegations suggest liability or wrongdoing by Teva.

248. Paragraph 248 of the Complaint recites legal conclusions, and so no answer is required. To the extent an answer is required, Teva admits that FDA requires New Drug Applications (“NDA”) to include substantial evidence of clinical safety and efficacy as defined by FDA.

249. Paragraph 249 of the Complaint recites legal conclusions, and so no answer is required. To the extent an answer is required, Teva admits that manufacturers submit an ANDA to the FDA for approval of new generic drugs, which must demonstrate therapeutic equivalence, including bioequivalence and pharmaceutical equivalence, as defined by FDA. Teva denies that ANDA submissions lack evidence of clinical safety and efficacy. Paragraph 249 also contains quotations of federal code which speak for themselves. To the extent an answer to the remaining

allegations is required, Teva denies the remainder of the allegations of Paragraph 249 to the extent they suggest liability or wrongdoing by Teva.

250. Paragraph 250 of the Complaint recites legal conclusions, and so no answer is required. To the extent an answer is required, Teva admits that therapeutic equivalence includes evidence that the drug products are bioequivalent and pharmaceutically equivalent, as defined by FDA. Teva admits that FDA's finding of therapeutic equivalence is evidence that the generic ANDA product is as safe and as effective as the RLD. Teva further admits each of its VCDs for sale on the U.S. market and which are the subject of this lawsuit were deemed by the FDA to be therapeutically equivalent, bioequivalent, and pharmaceutically equivalent to the RLD, and therefore deemed by FDA to be as safe and as effective as the RLD. To the extent a response to the remaining allegations is required, Teva denies the remaining allegations of Paragraph 250.

251. Paragraph 251 of the Complaint recites legal conclusions, and so no answer is required. To the extent an answer is required, Teva admits that ANDA submissions must include specific information set forth by FDA, which includes but is not limited to stability data. To the extent a response to the remaining allegations is required, Teva denies the remaining allegations of Paragraph 251 to the extent the allegations suggest liability or wrongdoing by Teva.

252. Paragraph 252 of the Complaint recites legal conclusions, and so no answer is required. Paragraph 252 of the Complaint otherwise refers to regulations, the contents of which speak for themselves. Teva denies the remaining allegations of Paragraph 252 to the extent the allegations suggest liability or wrongdoing by Teva.

253. Paragraph 253 of the Complaint recites legal conclusions, and so no answer is required. Paragraph 253 of the Complaint otherwise refers to regulations, the contents of which

speak for themselves. Teva denies the remaining allegations of Paragraph 253 to the extent the allegations suggest liability or wrongdoing by Teva.

254. Paragraph 254 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations contained in Paragraph 254 of the Complaint.

255. Paragraph 255 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations contained in Paragraph 255 of the Complaint.

256. Paragraph 256 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations contained in Paragraph 256 of the Complaint.

257. Paragraph 257 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations contained in Paragraph 257 of the Complaint.

258. Paragraph 258 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, Teva denies the allegations contained in Paragraph 258 of the Complaint.

259. Teva denies the allegations contained in Paragraph 259 of the Complaint.

260. Teva denies the allegations of Paragraph 260 of the Complaint.

261. Paragraph 261 recites legal conclusions, and so no answer is required. To the extent an answer is required, denied as stated. Teva denies the allegations of Paragraph 261 to the extent the allegations suggest liability or wrongdoing by Teva.

262. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 262 of the Complaint, and therefore denies same.

263. Teva admits that VCDs are indicated for the treatment of hypertension, treatment of heart failure, and reduction of cardiovascular mortality in clinically stable patients following myocardial infarction. Teva is without knowledge or information sufficient to form a belief as to truth of the remaining allegations contained in Paragraph 263 of the Complaint, and therefore denies same.

264. Teva admits that its Valsartan and Valsartan hydrochlorothiazide are generic versions of DIOVAN and DIOVAN HCT. Teva is without knowledge or information sufficient to form a belief as to truth of the remaining allegations contained in Paragraph 264 of the Complaint, and therefore denies same.

265. Teva admits that its Valsartan amlodipine and Valsartan amlodipine hydrochlorothiazide are generic versions of EXFORGE and EXFORGE HCT. Teva is without knowledge or information sufficient to form a belief as to truth of the remaining allegations contained in Paragraph 265 of the Complaint, and therefore denies same.

266. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 266 of the Complaint, and therefore denies same.

267. Teva denies the allegations contained in Paragraph 267 of the Complaint.

268. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 268 of the Complaint, and therefore denies same.

269. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 269 of the Complaint, and therefore denies same.

270. Paragraph 270 of the Complaint recites legal conclusions, and so no answer is required. To the extent that an answer is required, denied.

271. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 271 of the Complaint, and therefore denies same.

272. Teva admits it filed an ANDA application for Valsartan on January 7, 2005. Teva denies the remaining allegations of Paragraph 272.

273. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 273 of the Complaint, and therefore denies same.

274. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 274 of the Complaint, and therefore denies same.

275. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 275 of the Complaint, and therefore denies same.

276. Paragraph 276 attempts to state a legal conclusion, to which no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 276 of the Complaint, and therefore denies same.

277. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 277 of the Complaint, and therefore denies same.

278. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 278 of the Complaint, and therefore denies same.

279. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 279 of the Complaint, and therefore denies same.



280. Teva admits it released a generic VCD to the U.S. market on or about January 2015. Teva is without knowledge or information sufficient to form a belief as to truth of the remaining allegations contained in Paragraph 280 of the Complaint, and therefore denies same.

281. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 281 of the Complaint, and therefore denies same.

282. Teva denies the allegations contained in Paragraph 282 of the Complaint.

283. Teva denies the allegations contained in Paragraph 283 of the Complaint.

284. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 284 of the Complaint, and therefore denies same.

285. Teva denies the allegations contained in Paragraph 285 of the Complaint to the extent they apply to Teva. Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 285.

286. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 286 of the Complaint, and therefore denies same.

287. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 287 of the Complaint, and therefore denies same.

288. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 288 of the Complaint, and therefore denies same.

289. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 289 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 289 to the extent the allegations suggest liability or wrongdoing by Teva.

290. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 290 of the Complaint, and therefore denies same.

291. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 291 of the Complaint, and therefore denies same.

292. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 292 of the Complaint, and therefore denies same.

293. Paragraph 293 attempts to quote from or characterize a writing, the contents of which speak for itself. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 293 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 293 to the extent the allegations suggest liability or wrongdoing by Teva.

294. Paragraph 294 attempts to quote from or characterize a writing, the contents of which speak for itself. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 294 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 294 to the extent the allegations suggest liability or wrongdoing by Teva.

295. Paragraph 295 attempts to quote from or characterize a writing, the contents of which speak for itself. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 295 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 295 to the extent the allegations suggest liability or wrongdoing by Teva.

296. Paragraph 296 attempts to quote from or characterize a writing, the contents of which speak for itself. To the extent a response is required, Teva is without knowledge or

information sufficient to form a belief as to truth of the allegations contained in Paragraph 296 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 296 to the extent the allegations suggest liability or wrongdoing by Teva.

297. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 297 of the Complaint, and therefore denies same.

298. Paragraph 298 attempts to quote from or characterize a writing, the contents of which speak for itself. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 298 of the Complaint, and therefore denies same.

299. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 299 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 299 to the extent the allegations suggest liability or wrongdoing by Teva.

300. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 300 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 300 to the extent the allegations suggest liability or wrongdoing by Teva.

301. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 301 of the Complaint, and therefore denies same.

302. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 302 of the Complaint, and therefore denies same.

303. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 303 of the Complaint, and therefore denies same.

304. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 304 of the Complaint, and therefore denies same.

305. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 305 of the Complaint, and therefore denies same.

306. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 306 of the Complaint, and therefore denies same.

307. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 307 of the Complaint, and therefore denies same.

308. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 308 of the Complaint, and therefore denies same.

309. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 309 of the Complaint, and therefore denies same.

310. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 310 of the Complaint, and therefore denies same.

311. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 311 of the Complaint, and therefore denies same.

312. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 312 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 312 to the extent the allegations suggest liability or wrongdoing by Teva.

313. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 313 of the Complaint, and therefore denies same.

314. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 314 of the Complaint, and therefore denies same.

315. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 315 of the Complaint, and therefore denies same.

316. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 316 of the Complaint, and therefore denies same.

317. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 317 of the Complaint, and therefore denies same.

318. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 318 of the Complaint, and therefore denies same.

319. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 319 of the Complaint, and therefore denies same.

320. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 320 of the Complaint, and therefore denies same.

321. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 321 of the Complaint, and therefore denies same.

322. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 322 of the Complaint, and therefore denies same.

323. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 323 of the Complaint, and therefore denies same.

324. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 324 of the Complaint, and therefore denies same.

325. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 325 of the Complaint, and therefore denies same.

326. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 326 of the Complaint, and therefore denies same.

327. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 327 of the Complaint, and therefore denies same.

328. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 328 of the Complaint, and therefore denies same.

329. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 329 of the Complaint, and therefore denies same.

330. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 330 of the Complaint, and therefore denies same.

331. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 331 of the Complaint, and therefore denies same.

332. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 332 of the Complaint, and therefore denies same.

333. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 333 of the Complaint, and therefore denies same.

334. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 334 of the Complaint, and therefore denies same.

335. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 335 of the Complaint, and therefore denies same.

336. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 336 of the Complaint, and therefore denies same.

337. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 337 of the Complaint, and therefore denies same.

338. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 338 of the Complaint, and therefore denies same.

339. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 339 of the Complaint, and therefore denies same.

340. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 340 of the Complaint, and therefore denies same.

341. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 341 of the Complaint, and therefore denies same.

342. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 342 of the Complaint, and therefore denies same.

343. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 343 of the Complaint, and therefore denies same.

344. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 344 of the Complaint, and therefore denies same.

345. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 345 of the Complaint, and therefore denies same.

346. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 346 of the Complaint, and therefore denies same. Teva

denies the allegations of Paragraph 346 to the extent the allegations suggest liability or wrongdoing by Teva.

347. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 347 of the Complaint, and therefore denies same.

348. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 348 of the Complaint, and therefore denies same.

349. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 349 of the Complaint, and therefore denies same.

350. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 350 of the Complaint, and therefore denies same.

351. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 351 of the Complaint, and therefore denies same.

352. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 352 of the Complaint, and therefore denies same.

353. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 353 of the Complaint, and therefore denies same.

354. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 354 of the Complaint, and therefore denies same.

355. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 355 of the Complaint, and therefore denies same.

356. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 356 of the Complaint, and therefore denies same.



357. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 357 of the Complaint, and therefore denies same.

358. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 358 of the Complaint, and therefore denies same.

359. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 359 of the Complaint, and therefore denies same.

360. Teva is without knowledge or information sufficient to form a belief as to truth of the allegations contained in Paragraph 360 of the Complaint, and therefore denies same.

361. Teva admits that NDMA is an odorless, yellow liquid.

362. Paragraph 362 attempts to quote from or characterize a document, which speaks for itself. In further response, Teva states the complaint misquotes from the cited EPA's Technical Fact Sheet cited. Except as thus stated, Teva admits that there are many alternative sources of NDMA, including various consumer and industrial products, as well as natural sources. Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 362 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 362 to the extent the allegations suggest liability or wrongdoing by Teva.

363. Teva admits that the EPA's Technical Fact Sheet NDMA fact sheet cited in paragraph 362 of the complaint states specifically, but without reference to pharmaceuticals, that "NDMA can be unintentionally produced in and released from industrial sources through chemical reactions, such as those that involve alkylamines. Potential industrial sources include amine manufacturing plants, tanneries, pesticide manufacturing plants, rubber and tire manufacturers, fish processing facilities, foundries, dye manufacturers and surfactant industries (ATSDR 1989)."

Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 363 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 363 to the extent the allegations suggest liability or wrongdoing by Teva.

364. Teva admits that the EPA's Technical Fact Sheet NDMA fact sheet cited in paragraph 364 of the complaint actually states specifically that "The American Conference of Governmental Industrial Hygienists (ACGIH) has classified NDMA as a Group A3 confirmed animal carcinogen with unknown relevance to humans (HSDB 2013)." Teva denies the allegations of Paragraph 364 to the extent the allegations suggest liability or wrongdoing by Teva.

365. Paragraph 365 attempts to quote from or characterize a document, which speaks for itself. Teva admits NDMA is a nitrosamine compound that has been studied for its carcinogenicity. Teva denies the allegations of Paragraph 365 to the extent the allegations suggest liability or wrongdoing by Teva.

366. Teva admits that the EPA's Technical Fact Sheet NDMA fact sheet cited in paragraph 366 of the complaint actually states, without reference to pharmaceuticals or medications, that "NDMA exposure may occur through (1) ingesting food that contains nitrosamines, such as smoked or cured meats and fish; (2) ingesting food that contains alkylamines, which can cause NDMA to form in the stomach; (3) drinking contaminated water; (4) drinking malt beverages (such as beer and whiskey) that may contain low levels of nitrosamines formed during processing; (5) using toiletry and cosmetic products such as shampoos and cleansers that contain NDMA; and (6) breathing or inhaling cigarette smoke. Workplace exposure can occur at tanneries, pesticide manufacturing plants and rubber and tire plants (ATSDR 1989, 1999)." Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth

of the allegations contained in Paragraph 366 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 366 to the extent the allegations suggest liability or wrongdoing by Teva.

367. Paragraph 367 attempts to quote from or characterize a document, which speaks for itself. Teva denies that there exists any reliable scientific evidence linking exposure to the levels of NDMA found in VCDs to liver damage in humans. Teva denies the allegations of Paragraph 367 to the extent the allegations suggest liability or wrongdoing by Teva.

368. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 368 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 368 to the extent the allegations suggest liability or wrongdoing by Teva.

369. Teva states that the Agency for Toxic Substances and Disease Registry's statement referenced in Paragraph 369 of the Complaint speaks for itself. Teva denies the quoted statements apply to Teva's VCDs or the levels of NDMA at issue. Teva denies the allegations in Paragraph 369 of the Complaint to the extent the allegations suggest liability or wrongdoing by Teva.

370. Teva admits NDMA is a nitrosamine compound that has been studied for its carcinogenicity. Teva denies that there exists any reliable scientific evidence linking exposure to the levels of NDMA found in VCDs to cancer in humans. Teva denies the allegations of Paragraph 370 to the extent the allegations suggest liability or wrongdoing by Teva.

371. Teva states that the FDA announcement referenced in Paragraph 371 of the Complaint speaks for itself. Teva denies the remaining allegations in Paragraph 371 of the Complaint to the extent the allegations suggest liability or wrongdoing by Teva.

372. Teva states that the EPA statement referenced in Paragraph 372 of the Complaint speaks for itself. Teva denies that there exists any reliable scientific evidence linking exposure to the levels of NDMA found in VCDs to cancer in humans. Teva denies the remaining allegations in Paragraph 372 of the Complaint to the extent the allegations suggest liability or wrongdoing by Teva.

373. Teva states that the WHO, FDA, and EMA statements referenced in Paragraph 373 of the Complaint speaks for itself. Teva denies that there exists any reliable scientific evidence linking exposure to the levels of NDMA found in VCDs to cancer in humans. Teva denies the remaining allegations in Paragraph 373 of the Complaint to the extent the allegations suggest liability or wrongdoing by Teva.

374. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 374 of the Complaint, and therefore denies same.

375. Teva admits NDEA is a nitrosamine compound that has been studied for its carcinogenicity. Teva denies that there exists any reliable scientific evidence linking exposure to the levels of NDEA found in VCDs to cancer in humans. Teva denies the allegations of Paragraph 375 to the extent the allegations suggest liability or wrongdoing by Teva.

376. Teva denies the allegations contained in Paragraph 376 of the Complaint.

377. Teva denies that there exists any reliable scientific evidence linking exposure to the levels of NDEA found in VCDs to liver damage or cancer in humans. Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 377 of the Complaint, and therefore denies same.

378. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 378 of the Complaint, and therefore denies same.

379. Teva denies that there exists any reliable scientific evidence linking exposure to the levels of NDEA found in VCDs to high-to-extreme toxicity from oral exposure. Teva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 379 of the Complaint, and therefore denies same.

380. Teva denies that there exists any reliable scientific evidence establishing NDEA at the levels found in VCDs as a human carcinogen. Teva states that the New Jersey Department of Health quote cited in Paragraph 380 speaks for itself. To the extent a response is required, Teva denies the allegations of Paragraph 380 to the extent the allegations suggest liability or wrongdoing by Teva.

381. Teva denies that there exists any reliable scientific evidence establishing NDEA at the levels found in VCDs as a human carcinogen. Teva states that the New Jersey Department of Health quote cited in Paragraph 381 speaks for itself. To the extent a response is required, Teva denies the allegations of Paragraph 381 to the extent the allegations suggest liability or wrongdoing by Teva.

382. Teva denies that there exists any reliable scientific evidence establishing NDEA at the levels found in VCDs as a human carcinogen. Teva denies the allegations of Paragraph 382 to the extent the allegations suggest liability or wrongdoing by Teva, and further states that the statements referenced in Paragraph 382, if such statements exist, speak for themselves.

383. Teva denies that there exists any reliable scientific evidence establishing NDEA at the levels found in VCDs as a human carcinogen. Teva states that the statements by the WHO, FDA and/or EMA speak for themselves. To the extent a response is required, Teva denies the allegations of Paragraph 383 to the extent the allegations suggest liability or wrongdoing by Teva.

384. Paragraph 384 of the Complaint references an online publication, the contents of which speak for themselves. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 384 of the Complaint, and therefore denies same.

385. Paragraph 385 of the Complaint references an online publication, the contents of which speak for themselves. To the extent a response is required, Teva denies the allegations contained in Paragraph 385 to the extent the allegations suggest liability or wrongdoing by Teva.

386. Teva denies that Teva, FDA or the pharmaceutical industry in general have been aware of the potential for formation of nitrosamines in pharmaceuticals as far back as 2005. Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 386 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 386 to the extent the allegations suggest liability or wrongdoing by Teva.

387. Teva states that the FDA quote cited in Paragraph 387 speaks for itself. To the extent a response is required, Teva denies the remaining allegations of Paragraph 387 to the extent the allegations suggest liability or wrongdoing by Teva.

388. Teva denies the allegations contained in Paragraph 388 of the Complaint.

389. Teva denies the allegations contained in Paragraph 389 of the Complaint.

390. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 390 of the Complaint related to ZHP's manufacturing process, and therefore denies same. Teva denies the remaining allegations of Paragraph 390 of the Complaint.

391. Teva states that the EMA quote cited in Paragraph 391 speaks for itself. To the extent a response is required, Teva admits NDMA was an unexpected impurity, denies the EMA has a similar jurisdiction to FDA, and Teva denies the remaining allegations of Paragraph 391 to the extent the allegations suggest liability or wrongdoing by Teva.

392. Teva denies the allegations contained in Paragraph 392 of the Complaint.

393. Teva denies the allegations contained in Paragraph 393 of the Complaint.

394. Teva states that the Federal Code quoted in Paragraph 394 speaks for itself. Teva denies the remaining allegations of Paragraph 394 of the Complaint.

395. Teva denies the allegations contained in Paragraph 395 of the Complaint.

396. Teva denies the allegations contained in Paragraph 396 of the Complaint.

397. Teva denies the allegations contained in Paragraph 397 of the Complaint.

398. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 398 of the Complaint, and therefore denies same.

399. Teva denies the allegations contained in Paragraph 399 of the Complaint.

400. Teva denies the allegations contained in Paragraph 400 of the Complaint.

401. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 401 of the Complaint, and therefore denies same.

402. Teva denies the allegations contained in Paragraph 402 of the Complaint.

403. Teva denies the allegations contained in Paragraph 403 of the Complaint.

404. Teva admits that on or about July 13, 2018, the FDA announced voluntary recalls of VCDs. Teva denies the remaining allegations of Paragraph 404 of the Complaint.

405. Teva admits that on or about July 27, 2018, the FDA announced voluntary recalls of VCDs. Teva denies the remaining allegations in Paragraph 405 of the Complaint to the extent the allegations suggest liability or wrongdoing by Teva.

406. Teva states that the FDA announcement referenced in Paragraph 406 of the Complaint speaks for itself. To the extent an answer is required, Teva denies the allegations in Paragraph 406 of the Complaint to the extent the allegations suggest liability or wrongdoing by Teva.

407. Teva states that the FDA announcements cited in Paragraph 407 of the Complaint speaks for itself. To the extent an answer is required, Teva denies the allegations in Paragraph 407 of the Complaint to the extent the allegations suggest liability or wrongdoing by Teva.

408. Teva denies the allegations contained in Paragraph 408 of the Complaint.

409. Teva denies the allegations contained in Paragraph 409 of the Complaint.

410. Teva denies the allegations contained in Paragraph 410 of the Complaint.

411. Teva admits that each of its VCDs for sale on the U.S. market were marketed under an ANDA approved by the FDA. Teva states that Paragraph 411 references a publicly available online document, which speaks for itself. Teva denies the remaining allegations of Paragraph 411 to the extent the allegations suggest liability or wrongdoing by Teva.

412. Paragraph 412 of the Complaint refers to documents and regulations, the contents of which speak for themselves. Teva otherwise denies the allegations in Paragraph 412 of the Complaint.

413. Teva admits that its generic VCDs were at all relevant times accompanied by FDA-approved labeling. Teva denies the remaining allegations in Paragraph 413 of the Complaint.



414. Teva admits that its generic VCDs were at all relevant times accompanied by FDA-approved labeling. Teva denies the remaining allegations in Paragraph 414 of the Complaint to the extent the allegations suggest liability or wrongdoing by Teva.

415. Teva denies the allegations in Paragraph 415 of the Complaint.

416. Teva denies the allegations in Paragraph 416 of the Complaint.

417. Teva denies the allegations in Paragraph 417 of the Complaint.

418. Teva denies the allegations in Paragraph 418 of the Complaint.

419. Teva denies the allegations in Paragraph 419 of the Complaint.

420. Teva denies the allegations in Paragraph 420 of the Complaint.

421. Teva denies the allegations in Paragraph 421 of the Complaint.

422. Teva denies the allegations in Paragraph 422 of the Complaint.

423. Teva denies the allegations in Paragraph 423 of the Complaint.

424. Teva denies the allegations in Paragraph 424 of the Complaint.

425. Teva denies the allegations in Paragraph 425 of the Complaint.

426. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 426 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 426 to the extent the allegations suggest liability or wrongdoing by Teva.

427. Teva denies the allegations in Paragraph 427 of the Complaint.

428. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 428 of the Complaint, and therefore denies same.

429. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 429 of the Complaint, and therefore denies same.

430. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 430 of the Complaint, and therefore denies same.

431. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 431 of the Complaint, and therefore denies same.

432. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 432 of the Complaint, and therefore denies same.

433. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 433 of the Complaint, and therefore denies same.

434. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without

knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 434 of the Complaint, and therefore denies same.

435. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 435 of the Complaint, and therefore denies same.

436. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 436 of the Complaint, and therefore denies same.

437. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 437 of the Complaint, and therefore denies same.

438. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 438 of the Complaint, and therefore denies same.

439. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 439 of the Complaint, and therefore denies same.

440. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 440 of the Complaint, and therefore denies same.

441. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 441 of the Complaint, and therefore denies same.

442. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 442 of the Complaint, and therefore denies same.

443. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 443 of the Complaint, and therefore denies same.

444. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 444 of the Complaint, and therefore denies same.

445. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without

knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 445 of the Complaint, and therefore denies same.

446. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 446 of the Complaint, and therefore denies same.

447. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 447 of the Complaint, and therefore denies same.

448. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 448 of the Complaint, and therefore denies same.

449. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 449 of the Complaint, and therefore denies same.

450. In response to the allegations in Paragraph 450 of the Complaint, Teva states that the unidentified statements referenced in Paragraph 450, if they exist, speak for themselves. Except as thus stated, Teva denies the allegations of Paragraph 450 of the Complaint.

451. In response to the allegations in Paragraph 451 of the Complaint, Teva states that the unidentified statements referenced in Paragraph 451, if they exist, speak for themselves. Teva

denies the allegations of Paragraph 451 of the Complaint to the extent the allegations suggest a breached warranty, misrepresentation, or other liability or wrongdoing by Teva.

452. In response to the allegations in Paragraph 452 of the Complaint, Teva states that the unidentified statements referenced in Paragraph 452, if they exist, speak for themselves. Teva denies the allegations of Paragraph 452 of the Complaint to the extent the allegations suggest a breached warranty, misrepresentation, or other liability or wrongdoing by Teva.

453. The allegations in Paragraph 453 of the Complaint refer to statements on a publicly accessible website and speak for themselves. Teva denies the allegations of Paragraph 453 of the Complaint to the extent the allegations suggest a breached warranty, misrepresentation, or other liability or wrongdoing by Teva.

454. The allegations in Paragraph 454 of the Complaint refer to statements on a publicly accessible website and speak for themselves. Teva denies the allegations of Paragraph 454 of the Complaint to the extent the allegations suggest a breached warranty, misrepresentation, or other liability or wrongdoing by Teva.

455. Teva admits each of its VCDs for sale on the U.S. market were deemed by the FDA to be bioequivalent to the RLD. The allegations in Paragraph 455 of the Complaint otherwise refer to unidentified statements attributed to Teva. Teva denies the allegations of Paragraph 455 of the Complaint to the extent the allegations suggest a breached warranty, misrepresentation, or other liability or wrongdoing by Teva.

456. In response to the allegations in Paragraph 456 of the Complaint, Teva states that the unidentified statements referenced in Paragraph 456, if they exist, speak for themselves. Teva denies the allegations of Paragraph 456 of the Complaint to the extent the allegations suggest a breached warranty, misrepresentation, or other liability or wrongdoing by Teva.

457. The allegations in Paragraph 457 of the Complaint refer to statements on a publicly accessible website and speak for themselves. Teva denies the allegations of Paragraph 457 of the Complaint to the extent the allegations suggest a breached warranty, misrepresentation, or other liability or wrongdoing by Teva.

458. In response to the allegations in Paragraph 458 of the Complaint, Teva states that the unidentified statements referenced in Paragraph 458, if they exist, speak for themselves. To the extent a response is required, Teva denies the allegations of Paragraph 458 of the Complaint to the extent the allegations suggest a breached warranty, misrepresentation, or other liability or wrongdoing by Teva.

459. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 459 of the Complaint, and therefore denies same.

460. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 460 of the Complaint, and therefore denies same.

461. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 461 of the Complaint, and therefore denies same.

462. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 462 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 462 to the extent the allegations suggest liability or wrongdoing by Teva.

463. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 463 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 463 to the extent the allegations suggest liability or wrongdoing by Teva.

464. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 464 of the Complaint, and therefore denies same.

465. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 465 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 465 to the extent the allegations suggest liability or wrongdoing by Teva.

466. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 466 of the Complaint, and therefore denies same.

467. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 467 of the Complaint, and therefore denies same.

468. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 468 of the Complaint, and therefore denies same.

469. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 469 of the Complaint, and therefore denies same.

470. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 470 of the Complaint, and therefore denies same.

471. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 471 of the Complaint, and therefore denies same.

472. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 472 of the Complaint, and therefore denies same.

473. Teva denies the allegations of Paragraph 473 to the extent the allegations attempt to characterize the actions or motivations of Teva. Except as thus stated, Teva is without



knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 473 of the Complaint, and therefore denies same.

474. The FDA document referenced in Paragraph 474 speaks for itself. Teva denies the allegations of Paragraph 474 to the extent the allegations attempt to characterize the actions or motivations of Teva. Except as thus stated, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 474 of the Complaint, and therefore denies same.

475. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 475 of the Complaint, and therefore denies same.

476. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 476 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 476 to the extent the allegations suggest liability or wrongdoing by Teva.

477. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 477 of the Complaint, and therefore denies same.

478. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 478 of the Complaint, and therefore denies same.

479. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 479 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 479 to the extent the allegations suggest liability or wrongdoing by Teva.

480. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 480 of the Complaint, and therefore denies same.

481. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 481 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 481 to the extent the allegations suggest liability or wrongdoing by Teva.

482. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 482 of the Complaint, and therefore denies same.

483. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 483 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 483 to the extent the allegations suggest liability or wrongdoing by Teva.

484. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 484 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 484 to the extent the allegations suggest liability or wrongdoing by Teva.

485. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 485 of the Complaint, and therefore denies same.

486. Paragraph 486 recites legal conclusions and/or attempts to set forth published guidance, statutory or regulatory requirements, which speak for themselves, and so no answer is required. To the extent that an answer is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 486 of the Complaint, and therefore denies same.

487. Paragraph 487 recites legal conclusions and/or attempts to set forth published guidance, statutory or regulatory requirements, which speak for themselves, and so no answer is

required. To the extent that an answer is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 487 of the Complaint, and therefore denies same.

488. Paragraph 488 recites legal conclusions and/or attempts to set forth published guidance, statutory or regulatory requirements, which speak for themselves, and so no answer is required. To the extent that an answer is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 488 of the Complaint, and therefore denies same.

489. Paragraph 489 recites legal conclusions and/or attempts to set forth published guidance, statutory or regulatory requirements, which speak for themselves, and so no answer is required. To the extent that an answer is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 489 of the Complaint, and therefore denies same.

490. Paragraph 490 recites legal conclusions and/or attempts to set forth published guidance, statutory or regulatory requirements, which speak for themselves, and so no answer is required. To the extent that an answer is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 490 of the Complaint, and therefore denies same.

491. Paragraph 491 recites legal conclusions and/or attempts to set forth published guidance, statutory or regulatory requirements, which speak for themselves, and so no answer is required. To the extent that an answer is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 491 of the Complaint, and therefore denies same.

492. Paragraph 492 recites legal conclusions and/or attempts to set forth published guidance, statutory or regulatory requirements, which speak for themselves, and so no answer is required. To the extent that an answer is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 492 of the Complaint, and therefore denies same.

493. Paragraph 493 recites legal conclusions and/or attempts to set forth published guidance, statutory or regulatory requirements, which speak for themselves, and so no answer is required. To the extent that an answer is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 493 of the Complaint, and therefore denies same.

494. Paragraph 494 recites legal conclusions and/or attempts to set forth published guidance, statutory or regulatory requirements, which speak for themselves, and so no answer is required. To the extent that an answer is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 494 of the Complaint, and therefore denies same.

495. Paragraph 495 recites legal conclusions and/or attempts to set forth published guidance, statutory or regulatory requirements, which speak for themselves, and so no answer is required. To the extent that an answer is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 495 of the Complaint, and therefore denies same.

496. Paragraph 496 includes references to a published document, which speaks for itself. Except as thus stated, Teva denies the allegations contained in Paragraph 496 of the Complaint.

497. Paragraph 497 includes references to a published document, which speaks for itself. Except as thus stated, Teva denies the allegations contained in Paragraph 497 of the Complaint.

498. Teva denies the allegations contained in Paragraph 498 of the Complaint.

499. Teva denies the allegations contained in Paragraph 499 of the Complaint.

500. Teva denies the allegations contained in Paragraph 500 of the Complaint.

501. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 501 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 501 to the extent the allegations suggest liability or wrongdoing by Teva.

502. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 502 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 502 to the extent the allegations suggest liability or wrongdoing by Teva.

503. Paragraph 503 recites legal conclusions and/or attempts to set forth statutory or regulatory requirements, which speak for themselves, and so no answer is required. To the extent that an answer is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 503 of the Complaint, and therefore denies same.

504. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 504 of the Complaint, and therefore denies same.

505. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 505 of the Complaint, and therefore denies same.

506. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 506 of the Complaint, and therefore denies same.

507. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 507 of the Complaint, and therefore denies same.

508. Paragraph 508 recites legal conclusions and/or attempts to set forth statutory or regulatory requirements, which speak for themselves, and so no answer is required. To the extent that an answer is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 508 of the Complaint, and therefore denies same.

509. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 509 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 509 to the extent the allegations suggest liability or wrongdoing by Teva.

510. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 510 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 510 to the extent the allegations suggest liability or wrongdoing by Teva.

511. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 511 of the Complaint, and therefore denies same.

512. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 512 of the Complaint, and therefore denies same.

513. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 513 of the Complaint, and therefore denies same.

514. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 514 of the Complaint, and therefore denies same.

515. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 515 of the Complaint, and therefore denies same.

516. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 516 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 516 to the extent the allegations suggest liability or wrongdoing by Teva.

517. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 517 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 517 to the extent the allegations suggest liability or wrongdoing by Teva.

518. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 518 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 518 to the extent the allegations suggest liability or wrongdoing by Teva.

519. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 519 of the Complaint, and therefore denies same.

520. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 520 of the Complaint, and therefore denies same.

521. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 521 of the Complaint, and therefore denies same.

522. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 522 of the Complaint, and therefore denies same.

523. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 523 of the Complaint, and therefore denies same.

524. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 524 of the Complaint, and therefore denies same.

525. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 525 of the Complaint, and therefore denies same.

526. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 526 of the Complaint, and therefore denies same.

527. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 527 of the Complaint, and therefore denies same.

528. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 528 of the Complaint, and therefore denies same.

529. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 529 of the Complaint, and therefore denies same.

530. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 530 of the Complaint, and therefore denies same.

531. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 531 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 531 to the extent the allegations suggest liability or wrongdoing by Teva.



532. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 532 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 532 to the extent the allegations suggest liability or wrongdoing by Teva.

533. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 533 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 533 to the extent the allegations suggest liability or wrongdoing by Teva.

534. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 534 of the Complaint, and therefore denies same.

535. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 535 of the Complaint, and therefore denies same.

536. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 536 of the Complaint, and therefore denies same.

537. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 537 of the Complaint, and therefore denies same.

538. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 538 of the Complaint, and therefore denies same.

539. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 539 of the Complaint, and therefore denies same.

540. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 540 of the Complaint, and therefore denies same.

541. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 541 of the Complaint, and therefore denies same.

542. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 542 of the Complaint, and therefore denies same.

543. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 543 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 543 to the extent the allegations suggest liability or wrongdoing by Teva.

544. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 544 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 544 to the extent the allegations suggest liability or wrongdoing by Teva.

545. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 545 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 545 to the extent the allegations suggest liability or wrongdoing by Teva.

546. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 546 of the Complaint, and therefore denies same.

547. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 547 of the Complaint, and therefore denies same.

548. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 548 of the Complaint, and therefore denies same.

549. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 549 of the Complaint, and therefore denies same.

550. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 550 of the Complaint, and therefore denies same.

551. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 551 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 551 to the extent the allegations suggest liability or wrongdoing by Teva.

552. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 552 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 552 to the extent the allegations suggest liability or wrongdoing by Teva.

553. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 553 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 553 to the extent the allegations suggest liability or wrongdoing by Teva.

554. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 554 of the Complaint, and therefore denies same.

555. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 555 of the Complaint, and therefore denies same.

556. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 556 of the Complaint, and therefore denies same.

557. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 557 of the Complaint, and therefore denies same.

558. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 558 of the Complaint, and therefore denies same.

559. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 559 of the Complaint, and therefore denies same.

560. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 560 of the Complaint, and therefore denies same.

561. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 561 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 561 to the extent the allegations suggest liability or wrongdoing by Teva.

562. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 562 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 562 to the extent the allegations suggest liability or wrongdoing by Teva.

563. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 563 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 563 to the extent the allegations suggest liability or wrongdoing by Teva.

564. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 564 of the Complaint, and therefore denies same.

565. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 565 of the Complaint, and therefore denies same.

566. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 566 of the Complaint, and therefore denies same.

567. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 567 of the Complaint, and therefore denies same.

568. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 568 of the Complaint, and therefore denies same.

569. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 569 of the Complaint, and therefore denies same.

570. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 570 of the Complaint, and therefore denies same.

571. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 571 of the Complaint, and therefore denies same.

572. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 572 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 572 to the extent the allegations suggest liability or wrongdoing by Teva.

573. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 573 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 573 to the extent the allegations suggest liability or wrongdoing by Teva.

574. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 574 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 574 to the extent the allegations suggest liability or wrongdoing by Teva.

575. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 575 of the Complaint, and therefore denies same.

576. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 576 of the Complaint, and therefore denies same.

577. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 577 of the Complaint, and therefore denies same.

578. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 578 of the Complaint, and therefore denies same.

579. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 579 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 579 to the extent the allegations suggest liability or wrongdoing by Teva.

580. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 580 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 580 to the extent the allegations suggest liability or wrongdoing by Teva.

581. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 581 of the Complaint, and therefore denies same. Teva

denies the allegations of Paragraph 581 to the extent the allegations suggest liability or wrongdoing by Teva.

582. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 582 of the Complaint, and therefore denies same.

583. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 583 of the Complaint, and therefore denies same.

584. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 584 of the Complaint, and therefore denies same.

585. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 585 of the Complaint, and therefore denies same.

586. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 586 of the Complaint, and therefore denies same.

587. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 587 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 587 to the extent the allegations suggest liability or wrongdoing by Teva.

588. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 588 of the Complaint, and therefore denies same.

589. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 589 of the Complaint, and therefore denies same.

590. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 590 of the Complaint, and therefore denies same.

591. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 591 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 591 to the extent the allegations suggest liability or wrongdoing by Teva.

592. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 592 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 592 to the extent the allegations suggest liability or wrongdoing by Teva.

593. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 593 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 593 to the extent the allegations suggest liability or wrongdoing by Teva.

594. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 594 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 594 to the extent the allegations suggest liability or wrongdoing by Teva.

595. Teva denies the allegations contained in Paragraph 595 of the Complaint.

596. Teva denies the allegations contained in Paragraph 596 of the Complaint.

597. Teva denies the allegations contained in Paragraph 597 of the Complaint.

598. Teva denies the allegations contained in Paragraph 598 of the Complaint.

599. Teva denies the allegations contained in Paragraph 599 of the Complaint.

600. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 600 of the Complaint, and therefore denies same. Teva



denies the allegations of Paragraph 600 to the extent the allegations suggest liability or wrongdoing by Teva.

601. Teva denies the allegations contained in Paragraph 601 of the Complaint.

602. Teva denies the allegations contained in Paragraph 602 of the Complaint.

603. The allegations in Paragraph 603 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies Plaintiffs have satisfied the requirements of Rule 23 for certification as a class action.

604. The allegations in Paragraph 604 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies Plaintiffs have satisfied the requirements of Rule 23 for certification as a class action.

605. The allegations in Paragraph 605 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 605 of the Complaint.

606. The allegations in Paragraph 606 and of the Complaint and its subparts call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 606 and its subparts of the Complaint.

607. The allegations in Paragraph 607 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 607 of the Complaint.

608. The allegations in Paragraph 608 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 608 of the Complaint, and therefore denies same.

609. The allegations in Paragraph 609 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 609 of the Complaint.

610. The allegations in Paragraph 610 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 610 of the Complaint.

611. The allegations in Paragraph 611 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 611 of the Complaint.

612. The allegations in Paragraph 612 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 612 of the Complaint.

613. The allegations in Paragraph 613 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 613 of the Complaint.

614. The allegations in Paragraph 614 and its subparts of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 614 and its subparts of the Complaint.

615. The allegations in Paragraph 615 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 615 of the Complaint.

616. The allegations in Paragraph 616 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 616 of the Complaint.

617. The allegations in Paragraph 617 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 617 of the Complaint.

618. The allegations in Paragraph 618 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 618 of the Complaint.

**FIRST CAUSE OF ACTION**  
**BREACH OF EXPRESS WARRANTIES**  
**(INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS**  
**MEMBERS AGAINST MANUFACTURER DEFENDANTS)**

619. Teva incorporates its answers to Paragraphs 1 through 618 of the Complaint as if fully stated herein.

620. Paragraph 620 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva admits that Plaintiffs have brought the above-captioned lawsuit but denies it meets the requirements of Rule 23.

621. Teva denies the allegations contained in Paragraph 621 of the Complaint.

622. Teva denies the allegations contained in Paragraph 622 of the Complaint.

623. Teva denies the allegations contained in Paragraph 623 of the Complaint.

624. Teva denies the allegations contained in Paragraph 624 of the Complaint.

625. Teva denies the allegations contained in Paragraph 625 of the Complaint.

626. The statutory authorities and Uniform Commercial Code citations contained in Paragraph 626 of the Complaint speak for themselves and do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 626 of the Complaint.

627. Paragraph 627 references a claim that has been dismissed and therefore does not require a response. To the extent a response is required, Teva admits the Complaint fails to state a claim for express warranty under Louisiana law.

628. Teva denies the allegations contained in Paragraph 628 of the Complaint.

629. Teva denies the allegations contained in Paragraph 629 of the Complaint.

630. Teva denies the allegations contained in Paragraph 630 of the Complaint.

631. Teva denies the allegations contained in Paragraph 631 of the Complaint.

632. Teva denies the allegations contained in Paragraph 632 of the Complaint.

**SECOND CAUSE OF ACTION**  
**BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY**  
**AND FITNESS**  
**(INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS**  
**MEMBERS AGAINST MANUFACTURER DEFENDANTS)**

633. Teva incorporates its answers to Paragraphs 1 through 632 of the Complaint as if fully stated herein.

634. Paragraph 634 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva admits that Plaintiffs have brought the above-captioned lawsuit.

635. The statutory authorities and Uniform Commercial Code citations contained in Paragraph 635 of the Complaint speak for themselves and do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 635 of the Complaint.

636. Paragraph 636 references claims that have been dismissed and therefore does not require a response. To the extent a response is required, Teva admits the Complaint fails to state a claim for implied warranty under Alabama, Arizona, Idaho, North Carolina, Tennessee and Louisiana law.

637. Teva denies the allegations contained in Paragraph 637 of the Complaint.

638. Teva denies the allegations contained in Paragraph 638 of the Complaint.

639. Teva denies the allegations contained in Paragraph 639 of the Complaint.

640. Teva denies the allegations contained in Paragraph 640 of the Complaint.

641. Teva denies the allegations contained in Paragraph 641 of the Complaint.

642. Teva denies the allegations contained in Paragraph 642 of the Complaint.

643. Teva denies the allegations contained in Paragraph 643 of the Complaint.

644. Teva denies the allegations contained in Paragraph 644 of the Complaint.

645. Teva denies the allegations contained in Paragraph 645 of the Complaint.

646. Paragraph 646 states a conclusion of law, to which no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 646 of the Complaint.

647. Paragraph 647 states a conclusion of law, to which no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 647 of the Complaint.

648. Teva denies the allegations contained in Paragraph 648 of the Complaint.

649. Teva denies the allegations contained in Paragraph 649 of the Complaint.

650. Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 650 of the Complaint and therefore denies the same.

651. Teva denies the allegations contained in Paragraph 651 of the Complaint.

**THIRD CAUSE OF ACTION**  
**BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY**  
**AND FITNESS**  
**(INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS**  
**MEMBERS AGAINST WHOLESALER DEFENDANTS)**

652. Teva incorporates its answers to Paragraphs 1 through 651 of the Complaint as if fully stated herein.

653. Paragraph 653 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva admits that Plaintiffs have brought the above-captioned lawsuit but denies it satisfies the requirements of Rule 23.

654. The statutory authorities and Uniform Commercial Code citations contained in Paragraph 654 of the Complaint speak for themselves and do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 654 of the Complaint.

655. Paragraph 655 references claims that are directed at Defendants other than Teva and which have been dismissed and therefore does not require a response.

656. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 656 of the Complaint, and therefore denies same.

657. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 657 of the Complaint, and therefore denies same.

658. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 658 of the Complaint, and therefore denies same.

659. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 659 of the Complaint, and therefore denies same.

660. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 660 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 660 to the extent the allegations suggest liability or wrongdoing by Teva.

661. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva denies the allegations contained in Paragraph 661 of the Complaint.

662. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 662 of the Complaint, and therefore denies same.

663. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva denies the allegations contained in Paragraph 663 of the Complaint.

664. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 664 of the Complaint, and therefore denies same.

665. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 665 of the Complaint, and therefore denies same.

666. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva denies the allegations contained in Paragraph 666 of the Complaint.

667. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 667 of the Complaint, and therefore denies same.

668. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 668 of the Complaint, and therefore denies same.

669. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva denies the allegations contained in Paragraph 669.



**FOURTH CAUSE OF ACTION**  
**BREACH OF IMPLIED WARRANTIES OF MERCHANTABILITY**  
**AND FITNESS**  
**(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS**  
**ONLY AGAINST PHARMACY DEFENDANTS)**

670. Teva incorporates its answers to Paragraphs 1 through 669 of the Complaint as if fully stated herein.

671. Paragraph 671 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva admits that Plaintiffs have brought the above-captioned lawsuit but denies it satisfies the requirements of Rule 23..

672. The statutory authorities and Uniform Commercial Code citations contained in Paragraph 672 of the Complaint speak for themselves and do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 672 of the Complaint.

673. Paragraph 673 references claims that are directed at Defendants other than Teva and which have been dismissed and therefore does not require a response.

674. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 674 of the Complaint, and therefore denies same.

675. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 675 of the Complaint, and therefore denies same.

676. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 676 of the Complaint, and therefore denies same.

677. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva denies the allegations contained in Paragraph 677 of the Complaint.

678. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 678 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 678 to the extent the allegations suggest liability or wrongdoing by Teva.

679. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva denies the allegations contained in Paragraph 679 of the Complaint.

680. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 680 of the Complaint, and therefore denies same.

681. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva denies the allegations contained in Paragraph 681 of the Complaint.

682. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 682 of the Complaint, and therefore denies same.

683. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 683 of the Complaint, and therefore denies same.

684. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva denies the allegations contained in Paragraph 684 of the Complaint.

685. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 685 of the Complaint, and therefore denies same.

686. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 686 of the Complaint, and therefore denies same.

687. This paragraph sets forth claims that are directed at other Defendants and therefore does not require a response by Teva. To the extent a response is required, Teva denies the allegations contained in Paragraph 687.

**FIFTH CAUSE OF ACTION**  
**FRAUD (AFFIRMATIVE MISREPRESENTATION, OMISSION, AND**  
**CONCEALMENT)**  
**(INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS**  
**MEMBERS AGAINST MANUFACTURER DEFENDANTS)**

688. Teva incorporates its answers to Paragraphs 1 through 687 of the Complaint as if fully stated herein.

689. Paragraph 689 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva admits that Plaintiffs have brought the above-captioned lawsuit but denies it satisfies the requirements of Rule 23.

690. Paragraph 690 references claims that have been dismissed and therefore does not require a response. To the extent a response is required, Teva admits that the Complaint fails to state a claim for fraud under Louisiana law.

691. Teva denies the allegations contained in Paragraph 691 of the Complaint.

692. Teva denies the allegations contained in Paragraph 692 of the Complaint.

693. Teva denies the allegations contained in Paragraph 693 of the Complaint.

694. Teva denies the allegations contained in Paragraph 694 of the Complaint.

695. Teva denies the allegations contained in Paragraph 695 of the Complaint.

696. Teva denies the allegations contained in Paragraph 696 of the Complaint.

697. Teva denies the allegations contained in Paragraph 697 of the Complaint.

698. Teva denies the allegations contained in Paragraph 698 of the Complaint.

699. Teva denies the allegations contained in Paragraph 699 of the Complaint.

700. Teva denies the allegations contained in Paragraph 700 of the Complaint.

701. Teva denies the allegations contained in Paragraph 701 of the Complaint.

702. Teva denies the allegations contained in Paragraph 702 of the Complaint.

**SIXTH CAUSE OF ACTION**  
**NEGLIGENT MISREPRESENTATION AND OMISSION**  
**(INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS**  
**MEMBERS AGAINST MANUFACTURER DEFENDANTS)**

703. Teva incorporates its answers to Paragraphs 1 through 702 of the Complaint as if fully stated herein.

704. Paragraph 704 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva admits that Plaintiffs have brought the above-captioned lawsuit but denies it satisfies the requirements of Rule 23.

705. Paragraph 705 references claims that have been dismissed and therefore does not require a response. To the extent a response is required, Teva admits the Complaint fails to state a claim for negligent misrepresentation under Louisiana law.

706. Teva denies the allegations contained in Paragraph 706 of the Complaint.

707. Teva denies the allegations contained in Paragraph 707 of the Complaint.

708. Teva denies the allegations contained in Paragraph 708 of the Complaint.

709. Teva denies the allegations contained in Paragraph 709 of the Complaint.

710. Teva denies the allegations contained in Paragraph 710 of the Complaint.

711. Teva denies the allegations contained in Paragraph 711 of the Complaint.

712. Teva denies the allegations contained in Paragraph 712 of the Complaint.

713. Teva denies the allegations contained in Paragraph 713 of the Complaint.

714. Teva denies the allegations contained in Paragraph 714 of the Complaint.

715. Teva denies the allegations contained in Paragraph 715 of the Complaint.

716. Teva denies the allegations contained in Paragraph 716 of the Complaint.

717. Teva denies the allegations contained in Paragraph 717 of the Complaint.

718. Teva denies the allegations contained in Paragraph 718 of the Complaint.

719. Teva denies the allegations contained in Paragraph 719 of the Complaint.

**SEVENTH CAUSE OF ACTION**  
**VIOLATION OF STATE CONSUMER PROTECTION LAWS**  
**(INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS**  
**MEMBERS AGAINST MANUFACTURER DEFENDANTS)**

720. Teva incorporates its answers to Paragraphs 1 through 719 of the Complaint as if fully stated herein.

721. Paragraph 721 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva admits that Plaintiffs have brought the above-captioned lawsuit but denies it meets the requirements of Rule 23.

722. Paragraph 722 references claims that have been dismissed and therefore does not require a response. To the extent a response is required, Teva admits the Complaint fails to state a claim consumer protection violations under Louisiana law.

723. Teva denies the allegations contained in Paragraph 723 and each of its subparts of the Complaint.

724. Teva denies the allegations contained in Paragraph 724 of the Complaint.

725. Teva denies the allegations contained in Paragraph 725 of the Complaint.

726. Teva denies the allegations contained in Paragraph 726 of the Complaint.

727. Teva denies the allegations contained in Paragraph 727 of the Complaint.

728. Teva denies the allegations contained in Paragraph 728 of the Complaint.

729. Teva denies the allegations contained in Paragraph 729 of the Complaint.

730. Teva denies the allegations contained in Paragraph 730 of the Complaint.

731. Teva denies the allegations contained in Paragraph 731 of the Complaint.
732. Teva denies the allegations contained in Paragraph 732 of the Complaint.
733. Teva denies the allegations contained in Paragraph 733 of the Complaint.
734. Teva denies the allegations contained in Paragraph 734 of the Complaint.
735. Teva denies the allegations contained in Paragraph 735 of the Complaint.
736. Teva denies the allegations contained in Paragraph 736 of the Complaint.
737. Teva denies the allegations contained in Paragraph 737 of the Complaint.
738. Teva denies the allegations contained in Paragraph 738 of the Complaint.
739. Teva denies the allegations contained in Paragraph 739 of the Complaint.

**EIGHTH CAUSE OF ACTION**  
**VIOLATION OF STATE CONSUMER PROTECTION LAWS**  
**(INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS**  
**MEMBERS AGAINST WHOLESALER DEFENDANTS)**

740. Teva incorporates its answers to Paragraphs 1 through 739 of the Complaint as if fully stated herein.

741. Paragraph 741 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva admits that Plaintiffs have brought the above-captioned lawsuit but denies that it satisfies the requirements of Rule 23.

742. Paragraph 742 references claims that have been dismissed and that are directed at other Defendants, and therefore does not require a response.

743. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 743 and its subparts of the Complaint, and therefore denies same.

744. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 744 of the Complaint, and therefore denies same.

745. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 745 of the Complaint.

746. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 746 of the Complaint.

747. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 747 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 747 to the extent the allegations suggest liability or wrongdoing by Teva.

748. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 748 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 748 to the extent the allegations suggest liability or wrongdoing by Teva.

749. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without



knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 749 of the Complaint, and therefore denies same.

750. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva denies the allegation regarding the “act of sale of the VCDs by Manufacturer Defendants.” Teva is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 750 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 750 to the extent the allegations suggest liability or wrongdoing by Teva.

751. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 751 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 751 to the extent the allegations suggest liability or wrongdoing by Teva.

752. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 752 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 752 to the extent the allegations suggest liability or wrongdoing by Teva.

753. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 753 of the Complaint, and therefore denies same.

754. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 754 of the Complaint, and therefore denies same.

755. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 755 of the Complaint, and therefore denies same.

756. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 756 of the Complaint, and therefore denies same.

757. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 757 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 757 to the extent the allegations suggest liability or wrongdoing by Teva.

758. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 758 of the Complaint, and therefore denies same.

759. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without

knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 759 of the Complaint, and therefore denies same.

**NINTH CAUSE OF ACTION**  
**VIOLATION OF STATE CONSUMER PROTECTION LAWS**  
**(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS**  
**AGAINST RETAIL PHARMACY DEFENDANTS)**

760. Teva incorporates its answers to Paragraphs 1 through 759 of the Complaint as if fully stated herein.

761. Paragraph 761 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva admits that Plaintiffs have brought the above-captioned lawsuit but denies that it satisfies the requirements of Rule 23.

762. Paragraph 762 references claims that have been dismissed and which are directed at other Defendants, and therefore does not require a response.

763. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 763 and its subparts of the Complaint, and therefore denies same

764. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 764 of the Complaint, and therefore denies same.

765. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva denies the allegations contained in Paragraph 765 of the Complaint.

766. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 766 of the Complaint, and therefore denies same.

767. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 767 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 767 to the extent the allegations suggest liability or wrongdoing by Teva.

768. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 768 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 768 to the extent the allegations suggest liability or wrongdoing by Teva.

769. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 769 of the Complaint, and therefore denies same.

770. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 770 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 770 to the extent the allegations suggest liability or wrongdoing by Teva.

771. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 771 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 771 to the extent the allegations suggest liability or wrongdoing by Teva.

772. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 772 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 772 to the extent the allegations suggest liability or wrongdoing by Teva.

773. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 773 of the Complaint, and therefore denies same.

774. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 774 of the Complaint, and therefore denies same.

775. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 775 of the Complaint, and therefore denies same.

776. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 776 of the Complaint, and therefore denies same.

777. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 777 of the Complaint, and therefore denies same. Teva denies the allegations of Paragraph 777 to the extent the allegations suggest liability or wrongdoing by Teva.

778. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 778 of the Complaint, and therefore denies same.

779. The allegations contained in this Paragraph are directed at parties other than Teva and as such no response is required. To the extent a response is required, Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 779 of the Complaint, and therefore denies same.

**TENTH CAUSE OF ACTION**  
**UNJUST ENRICHMENT**  
**(INDIVIDUALLY AND ON BEHALF OF CONSUMER CLASS MEMBERS**  
**AGAINST ALL DEFENDANTS)**

780. Teva incorporates its answers to Paragraphs 1 through 779 of the Complaint as if fully stated herein.

781. Paragraph 781 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva admits that

Plaintiffs have brought the above-captioned lawsuit but denies that it satisfies the requirements of Rule 23.

782. Paragraph 782 references claims that have been dismissed and therefore does not require a response. To the extent a response is required, Teva admits the Complaint fails to state a claim for unjust enrichment under Louisiana law.

783. Teva denies the allegations contained in Paragraph 783 of the Complaint.

784. Teva denies the allegations contained in Paragraph 784 of the Complaint.

785. Teva denies the allegations contained in Paragraph 785 of the Complaint.

786. Teva denies the allegations contained in Paragraph 786 of the Complaint.

787. Paragraph 787 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva denies the allegations contained in Paragraph 787 of the Complaint.

788. Teva denies the allegations contained in Paragraph 788 of the Complaint.

**ELEVENTH CAUSE OF ACTION**  
**UNJUST ENRICHMENT**  
**(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST**  
**ALL DEFENDANTS EXCEPT PHARMACY DEFENDANTS)**

789. Teva incorporates its answers to Paragraphs 1 through 788 of the Complaint as if fully stated herein.

790. Paragraph 790 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva admits that Plaintiffs have brought the above-captioned lawsuit but denies that it satisfies the requirements of Rule 23.

791. Paragraph 791 references claims that have been dismissed and therefore does not require a response. To the extent a response is required, Teva admits that the Complaint fails to state a claim as to unjust enrichment under Louisiana law.

792. Teva denies the allegations contained in Paragraph 792 of the Complaint.

793. Teva denies the allegations contained in Paragraph 793 of the Complaint.

794. Teva denies the allegations contained in Paragraph 794 of the Complaint.

795. Teva denies the allegations contained in Paragraph 795 of the Complaint.

796. Paragraph 796 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva denies the allegations contained in Paragraph 796 of the Complaint.

797. Teva denies the allegations contained in Paragraph 797 of the Complaint.

**TWELFTH CAUSE OF ACTION**  
**NEGLIGENCE**  
**(INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS**  
**MEMBERS AGAINST MANUFACTURER DEFENDANTS)**

798. Teva incorporates its answers to Paragraphs 1 through 797 of the Complaint as if fully stated herein.

799. Paragraph 799 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva admits that Plaintiffs have brought the above-captioned lawsuit but denies that it satisfies the requirements of Rule 23.

800. Paragraph 800 references claims that have been dismissed and therefore does not require a response. To the extent a response is required, Teva admits that the Complaint fails to state a claim as to negligence under Louisiana law.

801. Teva denies the allegations contained in Paragraph 801 of the Complaint.



802. Teva denies the allegations contained in Paragraph 802 of the Complaint.

803. Teva denies the allegations contained in Paragraph 803 of the Complaint.

804. Teva denies the allegations contained in Paragraph 804 of the Complaint.

805. Teva denies the allegations contained in Paragraph 805 of the Complaint.

806. Teva denies the allegations contained in Paragraph 806 of the Complaint.

807. Teva denies the allegations contained in Paragraph 807 of the Complaint.

808. Teva denies the allegations contained in Paragraph 808 of the Complaint.

**THIRTEENTH CAUSE OF ACTION**  
**NEGLIGENCE PER SE**  
**(INDIVIDUALLY AND ON BEHALF OF CONSUMER AND TPP CLASS**  
**MEMBERS AGAINST MANUFACTURER DEFENDANTS)**

809. Teva incorporates its answers to Paragraphs 1 through 808 of the Complaint as if fully stated herein.

810. Paragraph 810 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva admits that Plaintiffs have brought the above-captioned lawsuit but denies that it satisfies the requirements of Rule 23.

811. Paragraph 811 references claims that have been dismissed and therefore does not require a response. To the extent a response is required, Teva admits that the Complaint fails to state a claim of negligence per se under Arkansas, Arizona, California, Massachusetts, Maine, Nebraska, Rhode Island, and Texas law.

812. Paragraph 812 references claims that have been dismissed and therefore does not require a response. To the extent a response is required, Teva admits that the Complaint fails to state a claim of negligence per se under Louisiana law.

813. Teva denies the allegations contained in Paragraph 813 of the Complaint.

814. Teva denies the allegations contained in Paragraph 814 of the Complaint.

815. Teva denies the allegations contained in Paragraph 815 of the Complaint.

816. Teva denies the allegations contained in Paragraph 816 of the Complaint.

817. Teva denies the allegations contained in Paragraph 817 of the Complaint.

818. Teva denies the allegations contained in Paragraph 818 of the Complaint.

**FOURTEENTH CAUSE OF ACTION**  
**STATE-LAW PRODUCT LIABILITY ACT CLAIM UNDER LOUISIANA LAW**  
**(INDIVIDUALLY AND ON BEHALF OF TPP CLASS MEMBERS AGAINST**  
**ALL DEFENDANTS, EXCEPT AS TO TPP CLASS MEMBERS AGAINST**  
**PHARMACY DEFENDANTS)**

819. Paragraph 819 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent a response is required, Teva denies the allegations in Paragraph 819 of the Complaint.

820. Paragraph 820 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva admits that Plaintiffs have brought the above-captioned lawsuit, but denies it satisfies the requirements of Rule 23. Teva incorporates its answers to Paragraphs 1 through 819 of the Complaint as if fully stated herein. Teva denies the remaining allegations in Paragraph 820 of the Complaint.

821. Paragraph 821 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent an answer is required, Teva denies the allegations in Paragraph 821 of the Complaint.

822. The allegations in Paragraph 822 of the Complaint call for a legal conclusion and thus do not require a response. To the extent a response is required, Teva denies the allegations in Paragraph 822.

823. Paragraph 823 does not set forth any allegation susceptible to admission or denial and, therefore, no answer is required. To the extent a response is required, Teva denies the allegations in Paragraph 823.

**PRAYER FOR RELIEF**

Teva denies that it is liable to Plaintiffs in any manner whatsoever and denies each and every allegation of the Paragraph to the extent said allegations imply any wrongdoing by Teva. Teva further denies Plaintiffs are entitled to any of the relief requested.

**GENERAL DENIAL**

Unless expressly admitted above, Teva denies each and every allegation contained in the Complaint.

**DEMAND FOR JURY TRIAL**

Defendants hereby demand a jury trial pursuant to Federal Rule of Civil Procedure 38(b).

**DEFENSES AND AFFIRMATIVE DEFENSES**

Teva further asserts that Plaintiffs' claims are barred, in whole or in part, by the defenses set forth below. By setting forth these defenses, Teva does not assume the burden of proving any fact, issue, or element of a cause of action where such burden properly belongs to Plaintiffs. Moreover, nothing herein stated is intended or shall be construed as an acknowledgement that any particular issue or subject matter is relevant to Plaintiffs' allegations. Teva reserves the right to plead any and all affirmative defenses that may be evident or appreciated after investigation and discovery in this matter. Without assuming any burden, it would not otherwise bear, Teva asserts the following Affirmative Defenses or matters of avoidance:

**FIRST DEFENSE**

Venue may be improper or inconvenient in this action.

**SECOND DEFENSE**

The Complaint, and each purported cause of action alleged therein, is barred because Plaintiffs lack standing to state the claims alleged in the Complaint and/or to assert the legal rights or interests of others.

**THIRD DEFENSE**

The Court lacks personal jurisdiction over Defendant Teva Pharmaceutical Industries Ltd.

**FOURTH DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001), and its progeny. Plaintiffs' claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution because of the pervasive federal regulation of prescription pharmaceuticals and their manufacturing, testing, marketing, and labeling under which these pharmaceuticals were approved.

**FIFTH DEFENSE**

Plaintiffs' claims are barred by the doctrine of immunity for prescription drugs, by the Commerce Clause, Article 1, Section 8 of the United States Constitution as an undue burden upon interstate commerce in that Plaintiffs have asserted claims for relief which, if granted, would constitute an impermissible burden on federal laws, regulations and policy relating to the development and marketing of prescription drugs in violation of the Supremacy Clause, Article VI, Clause 2 of the United States Constitution.

### **SIXTH DEFENSE**

The conduct of Teva in all activities with respect to the products at issue has been and is under the supervision of FDA. Accordingly, this action is barred by the doctrine of primary jurisdiction.

### **SEVENTH DEFENSE**

At all times relevant hereto, Teva's VCDs were a desirable, useful, safe, and effective pharmaceutical product indicated to treat Plaintiffs' medical conditions. Teva's VCDs were at all times accompanied by FDA-approved, legally compliant and adequate warnings regarding instructions for use and product risks, in the labeling and on the packaging for the product. The pharmaceutical VCDs were an unavoidably unsafe product as that term is defined within the meaning of the Restatement (Second) of Torts § 402A comment k. Comments j and k of the Restatement (Second) of Torts § 402A provide that unavoidably unsafe products, properly prepared and accompanied by proper directions and warnings, are neither defective nor unreasonably dangerous. Liability may not be imposed as to a properly manufactured, unavoidably unsafe pharmaceutical such as the VCDs at issue, provided it is distributed with information regarding the risks of which the manufacturer knew at the time of the manufacture, like those described in the FDA-approved labeling and packaging warnings, and liability may not be imposed for unwarned-of risks not known at the time of such design, manufacture, and sale of the product. Therefore, Plaintiffs' claims premised upon product defect and negligence are barred, in whole or in part, for the reasons set forth above.

### **EIGHTH DEFENSE**

The design, manufacture, labeling, and packaging of the subject prescription drug products were in conformity with the "state of the art" existing at the relevant time. Liability (including, but not limited to, strict liability) may not be imposed as to a properly manufactured prescription

drug distributed with adequate and appropriate warnings regarding the risks of which the manufacturer knew at the time of the manufacture, and liability may not be imposed for untold risks not known at the time of such design, manufacture, and sale of the subject prescription drug. Plaintiffs' claims are therefore barred, in whole or in part, by applicable state implied warranty law.

#### **NINTH DEFENSE**

Plaintiffs' claims are barred, in whole or in part, because the products at all times relevant hereto, complied with all applicable laws and regulations, as well as all applicable industry and FDA standards, statutes, rules, regulations and guidance at the time they were designed, manufactured, tested, marketed, and labeled. At the time the products were designed, manufactured, tested, marketed, labeled, and distributed they were approved by the FDA in all respects, including the design formulation requirements, labeling and warnings content, and manufacturing specifications to which they were subjected by FDA in granting and maintaining Abbreviated New Drug Application approval.

#### **TENTH DEFENSE**

There was no defect of any type in the VCDs at issue at the time they left Teva's possession. As such, Plaintiffs' claims are barred, in whole or in part, by applicable state implied warranty law.

#### **ELEVENTH DEFENSE**

Teva's VCDs' labeling was not false or misleading in any particular manner and the products accordingly were not misbranded.

**TWELFTH DEFENSE**

Teva's VCDs were not adulterated because "Adulteration" is a statutorily defined regulatory determination and FDA alone has the authority to make that determination. FDA never found Teva's VCDs adulterated at any time.

**THIRTEENTH DEFENSE**

Plaintiffs' claims are barred in whole or in part by the sophisticated user defense.

**FOURTEENTH DEFENSE**

Plaintiffs' claims are barred in whole or in part because, to the extent any misrepresentation was made, such misrepresentation was a bona fide error that occurred notwithstanding reasonable procedures maintained by Teva to avoid such misrepresentations.

**FIFTEENTH DEFENSE**

Plaintiffs' claims are barred in whole or in part because the alleged deceptive statement, to the extent it occurred, was made in good faith and without knowledge of its falsity and in reliance upon the oral or written representations of Teva's suppliers.

**SIXTEENTH DEFENSE**

Any allegedly fraudulent statement or conduct by Teva was not consumer oriented as required for liability under certain other state consumer protection statutes.

**SEVENTEENTH DEFENSE**

Plaintiffs' claims are barred, in whole or in part, by the doctrine of consent and/or ratification to the extent that Plaintiffs have received and paid for VCDs distributed by Teva after the initiation of this action or otherwise becoming aware of the events alleged in this action.

**EIGHTEENTH DEFENSE**

Plaintiffs' claims are barred, in whole or in part, to the extent Plaintiffs are not in privity of contract with Teva.

**NINETEENTH DEFENSE**

Plaintiffs' warranty-based claims are barred, in whole or in part, by Plaintiffs' failure to give proper or timely notice of any alleged defect or breach of warranty.

**TWENTIETH DEFENSE**

Teva asserts any and all defenses available under the Uniform Commercial Code ("UCC") now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709 and their state law equivalents.

**TWENTY-FIRST DEFENSE**

Plaintiffs' claims fail because neither the presence of the impurity at issue nor Plaintiffs' alleged damages were reasonably foreseeable.

**TWENTY-SECOND DEFENSE**

The injuries and/or damages claimed by Plaintiffs were the result of unavoidable circumstances that Teva could not have prevented.

**TWENTY-THIRD DEFENSE**

Plaintiffs' causes of action are barred, in whole or in part, to the extent discovery or investigation reveals that Plaintiffs' outcome was caused by intervening or superseding events, factors, occurrences, or conditions, which were in no way caused by Teva and for which Teva cannot be held liable.

**TWENTY-FOURTH DEFENSE**

Teva is not liable for injuries or damages caused by any product that it did not sell or distribute pursuant to the ANDAs that it held for VCDs.

**TWENTY-FIFTH DEFENSE**

Plaintiffs' causes of action are barred, in whole or in part, to the extent discovery or investigation reveals that Plaintiffs' outcome was caused by misuse, abuse, modification,



alteration, acts, or omissions of parties and non-parties over whom Teva had no control or authority, and, thus, any recovery should be reduced or barred by such parties' proportionate fault.

#### **TWENTY-SIXTH DEFENSE**

Plaintiffs' claims are barred or subject to set-off, in whole or in part, to the extent that Plaintiffs have released, settled with, recovered from, entered into an accord and satisfaction, or otherwise compromised their claims with any party or non-party other than Teva. Teva is entitled to a set-off for the entire amount of proceeds either of the Plaintiffs have or may recover from other resources.

#### **TWENTY-SEVENTH DEFENSE**

Plaintiffs' claims for punitive or other exemplary damages are barred in whole or in part by the due process clauses of any applicable state and United States Constitutions, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution. Any law, statute or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) unconstitutionally may permit recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not direct, or did not proximately cause harm, if any, to Plaintiffs; (4) unconstitutionally may permit recovery of punitive damages in an amount not reasonable or proportionate to the amount of harm, if any to Plaintiffs and to the amount of compensatory damages, if any; (5) unconstitutionally may permit

jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards for appellate review of punitive damages awards; (7) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *BMW of North America, Inc. v. Gore*, 517 US 559 (1996); *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S.1 (1991); and *State Farm Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

#### **TWENTY-EIGHTH DEFENSE**

Plaintiffs' claims are barred in whole or in part because punitive or other exemplary damages are not recoverable for the causes of action set forth in the Complaint, or in the alternative, the allegations of each cause of action in the Complaint are legally insufficient to support a claim for punitive or exemplary damages against Teva as to each cause of action.

#### **TWENTY-NINTH DEFENSE**

Plaintiffs' claims are barred in whole or in part because Teva did not act with the requisite level of conduct to be subjected to or that would otherwise support any punitive or exemplary damage award in this action. Accordingly, any award of punitive or exemplary damages would be improper under the United States and applicable state Constitutions and the common law and public policies of any applicable states.

#### **THIRTIETH DEFENSE**

No act or omission of Teva was malicious, willful, wanton, reckless, grossly negligent, or intentional, and therefore any award of punitive damages is barred.

#### **THIRTY-FIRST DEFENSE**

Plaintiffs' equitable claims are barred, in whole or in part, to the extent there is an adequate remedy at law.

**THIRTY-SECOND DEFENSE**

Any award to Plaintiffs in this action would constitute unjust enrichment.

**THIRTY-THIRD DEFENSE**

Some or all of the claims alleged by Plaintiffs are barred by the applicable statutes of limitation, statutes of repose, and/or the doctrine of laches.

**THIRTY-FOURTH DEFENSE**

The alleged injuries and damages of which Plaintiffs complain were not caused by any VCDs manufactured, sold, or distributed by Teva or any actions of Teva of any kind, but were caused by some other product, process, occurrence, event, service, and/or person over which Teva exercised no control or right of control.

**THIRTY-FIFTH DEFENSE**

The Complaint, and each purported cause of action alleged therein, does not state facts sufficient to certify a class. Therefore, this action is not properly brought as a class action.

**THIRTY-SIXTH DEFENSE**

The Plaintiffs are not proper representatives of the class they purport to represent and, accordingly, this action is not properly brought as a class action.

**THIRTY-SEVENTH DEFENSE**

Plaintiffs cannot maintain a representative or class action because the putative plaintiffs are not similarly situated.

**THIRTY-EIGHTH DEFENSE**

Teva hereby gives notice that it intends to rely upon such other defenses as may become available or appear during the course of proceedings in this case and hereby reserves the right to amend this Answer to assert such defenses. Teva also reserves the right to assert other and related defenses as may become available upon a determination of the law applicable to the action or any

part thereof or claim therein. Additionally, Teva hereby gives notice that it intends to rely upon and incorporate by reference any affirmative defenses that may be asserted by any codefendant in this lawsuit.

**REQUEST FOR RELIEF**

**WHEREFORE**, Teva requests the following relief:

1. That the Complaint be dismissed in its entirety, with prejudice and on the merits, as to all claims against Teva;
2. That Teva be awarded the attorneys' fees and costs incurred in connection with this action; and
3. For such other and further relief as the Court deems just and proper.

Dated: December 7, 2023

Respectfully Submitted:

By: /s/ Victoria Davis Lockard  
Victoria Davis Lockard

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Pharma, Inc., and Actavis LLC*

**CERTIFICATE OF SERVICE**

I hereby certify that I today caused to be served a copy of the within Answer and Affirmative Defenses to Plaintiffs' Third Amended Consolidated Economic Loss Class Action Complaint on December 7, 2023, via ECF.

Dated:

/s/ Gregory P. Coates